

In this context, the Examiner argues that the teaching of **Breitenbach et al.** and the disclosures of **Muller** and **Müller** are combinable because the references are concerned with high mixing in short times, and that a person of ordinary skill in the art would have been motivated to employ a planetary roller extruder in the process of **Breitenbach et al.** because **Muller** and/or **Müller** disclose that a planetary roller extruder achieves a high rate of mixing in a short amount of time. Applicants respectfully disagree with the Examiner's position.

The disclosure of **Muller** relates to a planetary roller extruder for thermoplastic materials and **Muller** explains that the planetary roller configuration of the extruder improves the pulling-in action<sup>1)</sup> and thereby reduces the risk of causing damage to the extruder spindles, especially when hard or tough materials are to be extruded<sup>2)</sup>. The disclosure of **Muller**, therefore, clearly fails to suggest or imply that a planetary roller configured extruder provides for a high rate of mixing in a short amount of time.

The disclosure of **Müller** relates to a two-stage extruder for thermoplastic materials which comprises a first vertical extrusion stage and a second horizontal extrusion stage. The vertical extrusion stage comprises a planetary plasticizing portion. In the first stage of the extruder, the gravitational force inherent in the material is exploited to achieve a uniform drawing-in action<sup>3)</sup>, and the planetary plasticizing portion serves to generate heat by internal shearing in order to fuse the molding materials<sup>4)</sup> and to sufficiently plasticize them<sup>5)</sup> before they are transferred to the second horizontal extrusion stage where the molding materials are homogenized<sup>6)</sup>. **Müller's** requirement that the extruder comprise a horizontal homogenization stage clearly indicates that the planetary portion of the vertical extrusion stage is insufficient to provide for a sufficiently high rate of mixing in a short amount of time.

The Examiner's position that person of ordinary skill in the art would have been motivated by the disclosures of **Muller** and/or **Müller**, or by the teaching of **Breitenbach et al.**, to employ a planetary roller extruder in the process of **Breitenbach et al.** is not deemed to be well taken. The teaching of **Breitenbach et al.** relates to the preparation of dosage forms which comprise pharmaceutically active agents and **Breitenbach et al.** inter alia point out that such agents are frequently shear and temperature sensitive<sup>7)</sup>. It is self evident and also addressed by **Breitenbach et al.** that it is essential where application forms of pharmaceutical agents are prepared that the dosage forms are homogeneous and have a uniform composition<sup>8)</sup>.

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1) Cf. col. 1, indicated lines 54 to 56, of **US 4,268,176**.

2) Cf. col. 3, indicated lines 4 to 6, of **US 4,368,176**.

3) Cf. col. 1, indicated lines 57 to 62, of **US 4,303,344**.

4) Cf. col. 1, indicated line 62, to col. 3, indicated line 9, of **US 4,303,344**.

5) Cf. col. 3, indicated lines 8 to 12, of **US 4,303,344**.

6) Cf. col. 4, indicated lines 47 to 49, of **US 4,303,344**.

7) Cf. in particular col. 1, indicated lines 43 to 46, of **US 6,221,368**. Cf. also page 2, indicated lines 13 to 23, of the application.

8) Cf. col. 1, indicated lines 36 to 39, of **US 6,221,368**.

According to the explanations given by **Müller**, a planetary roller configured extruder is particularly prone to generate heat and high shearing in the composition. A person of ordinary skill in the art would, therefore, conclude that a planetary roller configured extruder is unsuitable for the extrusion of molding materials which comprise pharmaceutically active ingredients. Moreover, **Müller** discloses that the action provided by the planetary roller portion of the extruder is insufficient to achieve a complete homogenization of the material. Since homogeneity of the composition is an essential prerequisite for a successful preparation of a pharmaceutical dosage form, the information provided by **Müller** –again– suggests that a planetary roller configured extruder cannot be employed successfully in a process for preparing the dosage form of a pharmaceutical agent. Rather than motivating a person of ordinary skill in the art to do what applicants have done, the information given by **Müller** suggests that the use of a planetary roller configured extruder in the preparation of a pharmaceutical dosage form according to the teaching of **Breitenbach et al.** would result in dosage forms which lack the homogeneity required for a pharmaceutical preparation and/or would cause damage to the pharmaceutical agent due to the high shear forces and the accompanying high temperatures encountered in a planetary roller extruder.

As explained in MPEP §2143, three basic criteria have to be met in order to establish a *prima facie* case of obviousness:

- (1) There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings,
- (2) there must be a reasonable expectation of success, and
- (3) the prior art reference or the combined references must teach or suggest all of the claim limitations.

Additionally, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and cannot be based on applicants' disclosure<sup>9)</sup>.

Where the teaching of **Breitenbach et al.** and the disclosure of **Muller** and/or **Müller** is concerned neither the required suggestion or motivation nor the necessary reasonable expectation of success is present. As such, the teaching of **Breitenbach et al.** taken in view of the disclosure of **Muller** and/or the disclosure of **Müller** clearly fails to establish that the subject matter of applicants' Claims 1 to 3 or Claims 1 to 5 was obvious within the meaning of Section 103(a) at the time applicants made the invention.

With regard to the Examiner's reference to the Court's holdings in *Stalego v. Heymes et al.*<sup>10)</sup> and the Board's decision in *Ex parte Pfeiffer*<sup>11)</sup> it is respectfully noted that the use of a planetary roller extruder as required in accordance with applicants' method certainly affects the method in a manipulative sense because it clearly affects the manner in which the polymeric binder and the

9) Cf. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438, 1442 (CAFC 1991).

10) 263 F.2d 334, 120 USPQ 473 (CCPA 1959)

11) 135 USPQ 31 (BPAI 1961)

pharmaceutical agent are mixed and plasticized. Accordingly, applicants' requisite requirement is deemed to be entitled to due consideration in the determination under Section 103(a).

In light of the foregoing and the arguments already presented by applicants in their previous paper, it is respectfully requested that the respective rejections be withdrawn. Favorable action is solicited.

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Respectfully submitted,

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